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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,958	07/30/2003	Thomas Wuske	71072	1769

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EXAMINER	
MOSS, KERI A	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,958	WUSKE ET AL.	
	Examiner	Art Unit	
	Keri A. Moss	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 30 July 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-13 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1, 7, 9 and 10, the phrase "generating one of an overpressure and a vacuum...to release the sample liquid..." is confusing. Does the phrase have the same meaning as "generating either an overpressure or a vacuum"? Also, how does a vacuum of a device release the sample fluid from the sampling tip?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Avakian (USP 3,985,032). In Figures 5 and 6, Avakian discloses a device and a process for collecting and releasing a sample liquid, the device comprising a sample collector 12' with a porous and dimensionally stable sampling tip 24 (column 2 lines 3-6) for taking up the sample liquid in the sampling tip and a pressure means, the

plunger of the micropipette, for generating an overpressure in the pores of the sampling tip to release the sample liquid from the sampling tip (column 1 lines 60-64). The pressure means, the micropipette plunger, is displaceable in relation to the sample collector. The overpressure in the pores of the sampling tip is generated by pushing together the pressure means and the sample collector (abstract). The overpressure is generated toward the inside of the cavity 14' of the sample collector 12'. The sample liquid is fed into an analytical and evaluating unit (column 1 lines 5-8).

5. Claims 1-3, 9-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kremer (USP 4,635,488). Kremer discloses a device and a process for collecting and releasing a sample liquid, the device comprising a sample collector 12, 14 with a porous and dimensionally stable sampling tip 12 for taking up the sample liquid in the sampling tip and a pressure means (column 3 lines 24-25) for generating an overpressure or a vacuum in the pores of the sampling tip 12 to release the sample liquid from the sampling tip. The pressure means brings about penetration of a reagent liquid from a reagent container into the pores during the pushing together of the pressure means and of the sample collector (Column 7 lines 50-52). The sampling tip 28 contacts an indicator zone 44,50, which indicates the uptake of the sample liquid by means of a moisture indicator that expands in the presence of moisture (column 8 lines 51-54). The moisture indicator is an indicator dye that shows a change in color in the presence of moisture (column 8 lines 51-66). Kremer also discloses a beaker-shaped reagent container 42 with an impermeable inner surface, wherein the sampling tip 12,

14, 34 and the beaker 42 enclose a volume. This reagent container 42 serves as an analytical and evaluating unit (column 7 lines 55-57).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer. Kremer discloses a device and a process for collecting and releasing a sample liquid, the device comprising a sample collector 12, 14 with a porous and dimensionally stable sampling tip 12 for taking up the sample liquid in the sampling tip and a pressure means (column 3 lines 24-25) for generating an overpressure or a vacuum in the pores of the sampling tip 12 to release the sample liquid from the sampling tip. In figure 15, Kremer also discloses a filter mixer 54 with a porous and incompressible filter reactor

said sampling tip 12 being complementary in shape to form a positive-locking connection of an approximately constant thickness. Kremer does not disclose the mean pore size of the porous glass or the packed chromatographic column. However, it is obvious to adjust pore size based on the size of the material you are filtering, to find the optimum workable range. See In re Boesche 617 F.2d 272, 205 USPQ 215 (CCPA 1980). It would also be obvious to have the pore size of the first filter 12 larger than the pore size of the second filter 54 to ensure passage of the desired compound through both filters and to gradually filter smaller contaminating particles and as optimization of a result effective variable. Therefore, it would have been obvious to modify Kremer to have the pore size of the first filter larger than the pore size of the second filter to gain the above advantages.

9. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer.

See Kremer supra.

While Kremer does not disclose a sampling tip that has an indicator zone, Kremer discloses a sampling tip that contacts an indicator zone 44, 50 which indicates the uptake of the sample liquid by means of a moisture indicator (Column 9 lines 47-53; column 8 lines 51-54). Kremer discloses two separate pieces whereas applicant claims one. Kremer discloses a concern for contamination during insertion and removal of the indicator 44,50 (column 10 lines 5-11). It would be obvious to integrate the two parts in order to eliminate the possibility of contamination of the sample. See also In re Larson,

144 USPQ 347, 349; 339 US 965 (CCPA 1965) (making one integrated structure in place of prior art with separate parts is obvious engineering choice).

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer in view of Nason (USP 4,978,504).

See Kremer supra.

Kremer does not disclose a process wherein the sample liquid is released by the step of generating an overpressure or vacuum toward the outside into a filter reactor. In figures 12 and 14, Nason discloses a process wherein the sample liquid is released by generating an overpressure toward the outside into a filter reactor 18,19. Nason teaches that the advantage of using filter reactor 18,19 is to filter the sample and reagent as required for certain tests (column 4 lines 56-63). Including the filter in the sample preparation process eliminates extra steps, limiting unnecessary exposure of the sample to laboratory personnel. It would be obvious to combine Kremer's process for collecting and releasing a sample fluid with Nason's process that includes a filter to gain the advantages of a sample preparation process that enables the sample to go through a greater variety of tests and additionally cuts down on sample exposure by laboratory personnel.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/417,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because a pneumatic device is not patentably distinct from a pressure means for generating one of an overpressure and a vacuum, but rather is such a pressure means.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KAM 1/31/06

LYLE A. ALEXANDER
PRIMARY EXAMINER